K012334

SEP 1 9 2001

510(k) Summary
Bionx Implants Inc.
Meniscus Arrow™

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
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Bionx Implants Ltd.
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Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland
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Date prepared: July 9th, 2001

Name of the device:

A.	Trade or Proprietary Name:	Contour Meniscus Arrow™
B.	Common Name:	Bioabsorbable Meniscus Arrow System
C.	Classification Name:	Biodegradable soft tissue fixation fastener
D.	Device Product Code:	MAI

Predicate Devices:

Bionx Implants Inc. Biofix® Biodegradable Meniscus Arrow System (K955768)
Bionx Implants Inc. Meniscus Arrow™ (K993453)

Intended Use:

The Contour Meniscus Arrow™ is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascular area of the meniscus (e.g. "red-red" and "red-white" zones) in conjunction with immobilization during healing.
The principles of operation is completely identical with the predicate device.

Device Description:

The device description of the Contour Meniscus Arrow™ is as follows.
- Composed of poly-L/D-polylactide copolymer
- Length 10, 13 and 16mm
- Diameter 1.1mm

The dimensions and shape subtstantially equivalent to the Biofix® Biodegradable Meniscus Arrow System (K955768) and Meniscus Arrow (K993453).

Substantial Equivalence:

The Contour Meniscus Arrow™ has the following similarities to the cleared Biofix® Biodegradable Meniscus Arrow System (K955768) and Meniscus Arrow (K993453):

- has the same indicated use
- uses the same operating principle
- incorporates the same basic design
- is manufactured by same machinery
- is packaged and sterilized using the same materials and processes
- has the same shelf life

In summary, the Contour Meniscus Arrow™ described is substantially equivalent to the predicate device. This change of raw material and minor modifications of the design does not raise any new problems concerning safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Bionx Implants, Inc.
c/o Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants, Ltd.
Hermiankatu 6-8 L
Tampere, Finland

Re: K012334/S001
Trade Name: Contour Meniscus Arrow
Regulation Number: Unclassified
Regulation Name: Fastener, fixation, biodegradable, soft tissue
Regulatory Class: Unclassified
Product Code: MAI
Dated: August 28, 2001
Received: August 30, 2001

Dear Mrs. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MS

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K012334

Device Name: Contour Meniscus Arrow™

Indications for Use:

The Contour Meniscus Arrow™ is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascular area of the meniscus (e.g. "red-red" and "red-white" zones) in conjunction with immobilization during healing.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012334